Title 46
PROFESSIONAL AND OCCUPATIONAL STANDARDS
Part XLV. Medical Professions
Subpart 3. Practice

Chapter 69. Prescription, Dispensation, and Administration of Medications

Subchapter A. Medications Used in the Treatment of Obesity

§6901. Scope of Subchapter

A. The rules of this Subchapter govern physician prescription, dispensation, administration, or other use of medications for weight control or weight reduction in the medical treatment of obesity.

AUTHORITY NOTE: Promulgated in accordance with R.S. 37:1270(A)(1), R.S. 37:1270(B)(6), and R.S. 37:1285(B).

HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Board of Medical Examiners, LR 18:744 (July 1992).

§6903. Definitions

A. As used in this Subchapter, the following terms shall have the meanings specified.

Anorectic¥a drug, medication, or substance used or intended for use as an appetite suppressant.

Schedule II Controlled Substance¥any substance so classified under and pursuant to regulations of the Drug Enforcement Administration (DEA), U.S. Department of Justice, 21 CFR §1308.12, or any substance which may hereafter be so classified by amendment or supplementation of such regulation.

Schedule III Anorectic¥benzphetamine, phendimetrazine, and any other substance now or hereafter classified as a Schedule III controlled substance under and pursuant to Federal DEA regulations, 21 CFR §1308.13, and which is indicated for use in the treatment of exogenous obesity by express approval of the U.S. Food and Drug Administration (FDA).

Schedule IV Anorectic¥fenfluramine, dexfenfluramine, phentermine, diethylpropion, mazindol, and any other substance now or hereafter classified as a Schedule IV controlled substance under and pursuant to federal DEA regulations, 21 CFR §1308.14 and which is indicated for use in the treatment of exogenous obesity by express approval of the FDA.

AUTHORITY NOTE: Promulgated in accordance with R.S. 37:1270(A)(1), R.S. 37:1270(B)(6), and R.S. 37:1285(B).

HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Board of Medical Examiners, LR 18:744 (July 1992), amended LR 23:1146 (September 1997).

§6905. Prohibitions

A. Absolute Prohibitions. A physician shall not prescribe, dispense, administer, supply, sell, give, or otherwise use to or for any person for the purpose of weight control or weight reduction in the treatment of obesity any amphetamine, dextroamphetamine, methamphetamine, or phenmetrazine drug or compound; any Schedule II controlled substance; human chorionic gonadotropin (HCG); thyroid hormones; diuretic medications; or any drug, medication, compound, or substance which is not indicated for use in the treatment of exogenous obesity by express approval of the U.S. Food and Drug Administration (FDA).

B. Schedule III-IV Anorectics. A physician shall not prescribe, dispense, or administer Schedule III or Schedule IV anorectics for the purpose of weight reduction or control in the treatment of obesity other than in strict conformity with each of the conditions and limitations prescribed by §6907 of this Subchapter.

AUTHORITY NOTE: Promulgated in accordance with R.S. 37:1270(A)(1), R.S. 37:1270(B)(6), and R.S. 37:1285(B).

HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Board of Medical Examiners, LR 18:744 (July 1992).

§6907. Use of Schedule III-IV Anorectics; Conditions; Limitations

A. General Conditions. A physician shall not prescribe, dispense, or administer a Schedule III or Schedule IV anorectic for the purpose of weight reduction or control in the treatment of obesity, except as an adjunct to a therapeutic regimen of weight reduction based on prescribed sound nutrition, caloric restriction, exercise, and behavior modification and otherwise in accordance with the FDA-approved indications for the medication and contraindications for unapproved combinations of anorectic agents. Schedule III-IV anorectics may be prescribed, dispensed, or administered only to an adult patient who is obese under recognized generally accepted criteria for determining obesity, whose obesity is exogenous and not primarily metabolic, who is not pregnant, who does not suffer from or have any disease or condition constituting a recognized contraindication for use of the substance, and who otherwise satisfies the conditions requisite to treatment with anorectics as prescribed by this section.

B. Requisite Prior Conditions. Before initiating treatment utilizing a Schedule III or IV anorectic with respect to any patient, a physician shall:

1. obtain a thorough prior history, including the patient's weight loss/gain history and prior efforts at weight reduction;

2. perform a thorough and complete physical examination;

3. determine that the patient is a proper candidate for weight reduction treatment and that the patient's obesity is not primarily metabolic;

4. rule out the presence of conditions recognized as contraindicating the use of anorectic medications, including, without limitation, pregnancy, hypertension, and hypersensitivity or idiosyncrasy to anorectics;

5. determine whether the patient has a history of or any tendency or propensity toward abuse of drugs, including alcohol;

6. determine that the patient has made a substantial good-faith effort at weight reduction under a *bona fide* program not utilizing anorectics;

7. take reasonable measures to ensure that the patient has not previously, in the course of treatment by one or more other practitioners, or otherwise, obtained and used anorectics in excess of the quantitative and durational limitations on the use of anorectics prescribed by §6907.E; and

8. provide the patient with a carefully prescribed diet, together with counseling on exercise and, as appropriate, other supportive or behavioral therapy.

C. Initiation of Anorectic Use. Upon completion and satisfaction of the conditions prescribed by §6907.A and B and upon the physician's judgment that the prescription, dispensation, or administration of an anorectic medication is medically warranted, the physician shall initiate anorectic treatment with the lowest dosage expected to be effective, as indicated by the manufacturer's FDA-approved dosage recommendation, employing a Schedule IV anorectic in preference to a Schedule III anorectic and refraining from use of Schedule III anorectics until and unless the anorectic initially used proves ineffective.

D. Continued Use of Anorectics. During the continued use of anorectics as permitted in this section, and subject to the limitations prescribed in §6907.E, the physician shall monitor the patient's progress closely and frequently, shall re-examine the patient not less frequently than monthly during such continued use and shall continue use of anorectics only if, upon each such re-examination, the patient demonstrates continued clinically significant weight loss since the prior examination.

E. Limitations on Use. A physician shall not prescribe or dispense Schedule III or IV anorectics to any patient:

1. in dosage greater than the maximum dosage indicated by the anorectic manufacturer's FDA-approved dosage recommendation;

2. in number or dosage units greater than an amount sufficient for use of the anorectic for a period of 30 days; or

3. for an aggregate period in excess of 12 weeks during any 12-month period; provided, however, that this limitation shall not be applicable with respect to Schedule IV anorectics.

F. Termination of Anorectic Use. Without regard to the permissible limitations otherwise prescribed by §6907.E, a physician shall refuse to initiate or re-initiate or shall terminate the use of anorectics with respect to a patient on any date that the physician determines, becomes aware, knows, or should know that:

1. the patient is not a proper candidate for the use of anorectics under the conditions and limitations prescribed by this section;

2. the patient has failed to demonstrate clinically significant weight loss since anorectics were last prescribed, dispensed, or administered to the patient by the physician;

3. the patient has developed tolerance to the appetite suppressant effect of the anorectic or has experienced euphoria followed by irritability or depression;

4. the patient has engaged in excessive use, misuse, or abuse of the anorectic or has otherwise consumed or disposed of the anorectics or any other controlled substance other than in strict compliance with the directions and indications for use given by the physician; or

5. the patient did not demonstrate clinically significant weight loss during a prior term of use of anorectics within the limitations of §6907.E.3 hereof.

G. Treatment Records. Satisfaction of each of the conditions and requirements prescribed by this section, all material elements of the patient's history, all significant findings from physical examination and diagnostic testing, and all medication and other treatment, including diet, prescribed by the physician, shall be accurately and completely recorded, documented, and dated, in writing, by the physician in the patient's record.

AUTHORITY NOTE: Promulgated in accordance with R.S. 37:1270(A)(1), R.S. 37:1270(B)(6), and R.S. 37:1285(B).

HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Board of Medical Examiners, LR 18:744 (July 1992), amended LR 23:1146 (September 1997).

§6909. Exemption of Controlled Scientific Studies

A. The prohibitions, conditions, and limitations on the use of Schedule III and Schedule IV anorectic medications prescribed by §6905.B and §6907 of this Subchapter shall not be applicable to a physician engaged in the conduct of a controlled scientific study of the efficacy of such medications in the medical treatment of obesity, provided that the physician is employed by or otherwise officially affiliated with an accredited medical school or college or other institution of higher learning located in the state of Louisiana, such study is conducted under the auspices of such school, college, or institution, and the interim and final results of such study are furnished to the board in writing.

AUTHORITY NOTE: Promulgated in accordance with R.S. 37:1270(A)(1), R.S. 37:1270(B)(6), and R.S. 37:1285(B).

HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Board Of Medical Examiners, LR 18:744 (July 1992).

§6911. Exceptions in Individual Cases

A. Availability of Exceptions. Upon written application to the board made in accordance with this Subsection, the board may authorize a physician, with respect to an identified individual patient, to exceed or otherwise depart from the prohibitions, conditions, and limitations on the use of Schedule III or Schedule IV anorectics otherwise prescribed by §6905.B and §6907 of this Subchapter.

B. Form, Content of Application for Exception. An application for board approval of an individual exception from the provisions of this Subchapter shall be submitted to the board's medical consultant in writing and shall contain:

1. individual identification of the patient to whom the physician proposes to prescribe, dispense, or administer anorectics other than in accordance with the provisions of this Subchapter;

2. a summary of the patient's medical and weight loss/gain history;

3. a complete copy of the patient's medical record, including a record of all anorectic medications prescribed, dispensed, or administered to or for the patient within 24 months prior to the application;

4. a statement by the physician of the specific manner in which the physician proposes to deviate from the provisions of this Subchapter respecting the prescription, dispensation, and administration of anorectic medications, together with a statement by the physician of the medical facts and circumstances deemed by the physician to justify such departure; and

5. such other information and documentation as the board or its medical consultant may request.

C. Board Action. The board may deny, grant, or grant in part any application for exception in an individual case made under this section. The board's action on any such application shall be stated in writing and shall specify the manner and extent to which the physician shall be authorized to depart from the provisions of this Subchapter and the period of time during which such authorized exception shall be effective. A physician who makes application to the board under this section shall not deviate from the prohibitions, conditions, and limitations provided in this Subchapter except following receipt of written authorization from the board or other than pursuant to the specifications and limitations of such authorization.

AUTHORITY NOTE: Promulgated in accordance with R.S. 37:1270(A)(1), R.S. 37:1270(B)(6), and R.S. 37:1285(B).

HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Board of Medical Examiners, LR 18:745 (July 1992).

§6913. Effect of Violation

A. Any violation of or failure of compliance with the provisions of this Subchapter, §§6901-6913, shall be deemed a violation of R.S. 37:1285.A(6) and (29), providing cause for the board to suspend or revoke, refuse to issue, or impose probationary or other restrictions on any license or permit held or applied for by a physician culpable of such violation.

AUTHORITY NOTE: Promulgated in accordance with R.S. 37:1270(A)(1), R.S. 37:1270(B)(6), and R.S. 37:1285(B).

HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Board of Medical Examiners, LR 18:746 (July 1992).

Subchapter B. Medications Used in the Treatment of Non-Cancer-Related Chronic or Intractable Pain

§6915. Scope of Subchapter

A. The Rules of this Subchapter govern physician responsibility for providing effective and safe pain control for patients with noncancer-related chronic or intractable pain.

AUTHORITY NOTE: Promulgated in accordance with R.S. 37:1270(A)(1), 1270(B)(6) and 1285(B).

HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Board of Medical Examiners LR 23:727 (June 1997), amended LR 26:693 (April 2000).

§6917. Definitions

A. As used in this Subchapter, unless the content clearly states otherwise, the following terms and phrases shall have the meanings specified.

Board¥the Louisiana State Board of Medical Examiners.

Chronic Pain¥pain which persists beyond the usual course of a disease, beyond the expected time for healing from bodily trauma, or pain associated with a long term-incurable or intractable medical illness or disease.

Controlled Substance¥any substance defined, enumerated or included in federal or state statute or regulations 21 C.F.R. §§1308.11-15 or R.S. 40:964, or any substance which may hereafter be designated as a controlled substance by amendment or supplementation of such regulations and statute.

Diversion¥the conveyance of a controlled substance to a person other than the person to whom the drug was prescribed or dispensed by a physician.

Intractable Pain¥a chronic pain state in which the cause of the pain cannot be eliminated or successfully treated without the use of controlled substance therapy and, which in the generally accepted course of medical practice, no cure of the cause of pain is possible or no cure has been achieved after reasonable efforts have been attempted and documented in the patient s medical record.

Noncancer-Related Pain¥that pain which is not directly related to symptomatic cancer.

Physical Dependence¥the physiological state of neuroadaptation to controlled substance which is characterized by the emergence of a withdrawal syndrome if the controlled substance use is stopped or decreased abruptly, or if an antagonist is administered. Withdrawal may be relieved by readministration of the controlled substance.

Physician¥physicians and surgeons licensed by the Board.

Protracted Basis¥utilization of any controlled substance for the treatment of noncancer-related chronic or intractable pain for a period in excess of 12 weeks during any 12-month period.

Substance Abuse (may also be referred to by the term *Addiction*)¥a compulsive disorder in which an individual becomes preoccupied with obtaining and using a substance, despite adverse social, psychological, and/or physical consequences, the continued use of which results in a decreased quality of life. The development of controlled substance tolerance or physical dependence does not equate with substance abuse or addiction.

Tolerance¥refers to the physiologic state resulting from regular use of a drug in which an increased dosage is needed to produce the same effect or a reduced effect is observed with a constant dose. Controlled substance tolerance refers to the need to increase the dose of the drug to achieve the same level of analgesia. Controlled substance tolerance may or may not be evident during controlled substance treatment.

AUTHORITY NOTE: Promulgated in accordance with R.S. 37:1270(A)(1), 1270(B)(6) and 1285(B).

HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Board of Medical Examiners LR 23:727 (June 1997), amended LR 26:693 (April 2000).

§6919. General Conditions/Prohibitions

A. The treatment of noncancer-related chronic or intractable pain with controlled substances constitutes legitimate medical therapy when provided in the course of professional medical practice and when fully documented in the patient's medical record. A physician duly authorized to practice medicine in Louisiana and to prescribe controlled substances in this state shall not, however, prescribe, dispense, administer, supply, sell, give, or otherwise use for the purpose of treating such pain, any controlled substance unless done in strict compliance with applicable state and federal laws and the rules enumerated in this Subchapter.

AUTHORITY NOTE: Promulgated in accordance with R.S. 37:1270(A)(1), R.S. 37:1270(B)(6) and R.S. 37:1285(B).

HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Board of Medical Examiners LR 23:727 (June 1997), amended LR 26:694 (April 2000).

§6921. Use of Controlled Substances, Limitations

A. Requisite Prior Conditions. In utilizing any controlled substance for the treatment of noncancer-related chronic or intractable pain on a protracted basis, a physician shall comply with the following rules.

1. Evaluation of the Patient. Evaluation of the patient shall initially include relevant medical, pain, alcohol and substance abuse histories, an assessment of the impact of pain on the patient's physical and psychological functions, a review of previous diagnostic studies, previously utilized therapies, an assessment of coexisting illnesses, diseases, or conditions, and an appropriate physical examination.

2. Medical Diagnosis. A medical diagnosis shall be established and fully documented in the patient's medical record, which indicates not only the presence of noncancer-related chronic or intractable pain, but also the nature of the underlying disease and pain mechanism if such are determinable.

3. Treatment Plan. An individualized treatment plan shall be formulated and documented in the patient's medical record which includes medical justification for controlled substance therapy. Such plan shall include documentation that other medically reasonable alternative treatments for relief of the patient's noncancer-related chronic or intractable pain have been considered or attempted without adequate or reasonable success. Such plan shall specify the intended role of controlled substance therapy within the overall plan, which therapy shall be tailored to the individual medical needs of each patient.

4. Informed Consent. A physician shall ensure that the patient and/or his guardian is informed of the benefits and risks of controlled substance therapy. Discussions of risks and benefits should be noted in some format in the patient's record.

B. Controlled Substance Therapy. Upon completion and satisfaction of the conditions prescribed in §6921.A, and upon a physician's judgment that the prescription, dispensation, or administration of a controlled substance is medically warranted, a physician shall adhere to the following rules.

1. Assessment of Treatment Efficacy and Monitoring. Patients shall be seen by the physician at appropriate intervals, not to exceed 12 weeks, to assess the efficacy of treatment, assure that controlled substance therapy remains indicated, and evaluate the patient's progress toward treatment objectives and any adverse drug effects. Exceptions to this interval shall be adequately documented in the patient's record. During each visit, attention shall be given to the possibility of decreased function or quality of life as a result of controlled substance treatment. Indications of substance abuse or diversion should also be evaluated. At each visit, the physician should seek evidence of under treatment of pain.

2. Drug Screen. If a physician reasonably believes that the patient is suffering from substance abuse or that he is diverting controlled substances, the physician shall obtain a drug screen on the patient. It is within the physician's discretion to decide the nature of the screen and which type of drug(s) to be screened.

3. Responsibility for Treatment. A single physician shall take primary responsibility for the controlled substance therapy employed by him in the treatment of a patient's noncancer-related chronic or intractable pain.

4. Consultation. The physician should be willing to refer the patient as necessary for additional evaluation and

treatment in order to achieve treatment objectives. Special attention should be given to those pain patients who are at risk for misusing their medications and those whose living arrangements pose a risk for medication misuse or diversion. The management of pain in patients with a history of substance abuse or with a comorbid psychiatric disorder may require extra care, monitoring, documentation, and consultation with or referral to an expert in the management of such patients.

5. Medications Employed. A physician shall document in the patient's medical record the medical necessity for the use of more than one type or schedule of controlled substance employed in the management of a patient's noncancer-related chronic or intractable pain.

6. Treatment Records. A physician shall document and maintain in the patient's medical record, accurate and complete records of history, physical and other examinations and evaluations, consultations, laboratory and diagnostic reports, treatment plans and objectives, controlled substance and other medication therapy, informed consents, periodic assessments, and reviews and the results of all other attempts at analgesia which he has employed alternative to controlled substance therapy.

7. Documentation of Controlled Substance Therapy. At a minimum, a physician shall document in the patient's medical record the date, quantity, dosage, route, frequency of administration, the number of controlled substance refills authorized, as well as the frequency of visits to obtain refills.

C. Termination of Controlled Substance Therapy. Evidence or behavioral indications of substance abuse or diversion of controlled substances shall be followed by tapering and discontinuation of controlled substance therapy. Such therapy shall be reinitiated only after referral to and written concurrence of the medical necessity of continued controlled substance therapy by an addiction medicine specialist, a pain management specialist, a psychiatrist, or other substance abuse specialist based upon his physical examination of the patient and a review of the referring physician's medical record of the patient.

AUTHORITY NOTE: Promulgated in accordance with R.S. 37:1270(A)(1), R.S. 37:1270(B)(6), and R.S. 37:1285(B).

HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Board of Medical Examiners, LR 23:727 (June 1997), amended LR 26:694 (April 2000).

§6923. Effect of Violation

A. Any violation of or failure of compliance with the provisions of this Subchapter, §§6915-6923, shall be deemed a violation of R.S. 37:1285.A(6) and (14), providing cause for the board to suspend or revoke, refuse to issue, or impose probationary or other restrictions on any license held or applied for by a physician to practice medicine in the state of Louisiana culpable of such violation.

AUTHORITY NOTE: Promulgated in accordance with R.S. 37:1270(A)(1), R.S. 37:1270(B)(6), and R.S. 37:1285(B).

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